

REMARKS

The present Office Action addresses claims 1-12 and 14-21, rejecting claims 18, 19, and 21 as being anticipated by Kuslich (U.S. Patent No. 5,571,189), and rejecting claims 18-21 as being unpatentable over Stubstad (U.S. Patent 3,867,728) as obvious. Claim 21 also stands rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claim 8 of U.S. Patent 6,997,956. Applicant notes with appreciation the Examiner's indication that claims 1-12 and 14-17 contain allowable subject matter, and would be allowed if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

Applicant traverses the rejections, and amends all of the claims.

By this amendment, all of the claims are amended to recite a method for the therapeutic or prophylactic treatment of a spinal disc annulus having an aperture comprising, inter alia, the steps of providing a device comprising a biocompatible material for placement in and across the aperture such that said material forms a bridge providing a platform for a traverse of fibroblasts or other normal cells of repair existing in and around the various layers of the spinal disc annulus, and acutely securing the device to said disc annulus. Support for these limitations can be found throughout the specification, and specifically at paragraph nos. [012], [014], [041], [042], [045], [046], and [059] to [061] of the publication of this application, or U.S. Publication No. 2002/0123807. Among other things, the cited paragraphs disclose the use of various

fixation devices for acute securement of the therapeutic or prophylactic device to the annulus fibrosus. Accordingly, no new matter is added by these amendments.

Applicants respectfully request reconsideration and withdrawal of all of the pending rejections in view of the amendments and the following remarks.

The Prior Art Rejections

The present Office Action rejects claims 1-12 and 14-21, rejecting claims 18, 19, and 21 under 35 U.S.C. §102(b) as anticipated by Kuslich (U.S. Patent No. 5,571,189), and claims 18-21 as being unpatentable over Stubstad (U.S. Patent 3,867,728) under 35 U.S.C. § 103(a) as obvious. For the following reasons, Applicant requests reconsideration and withdrawal of the rejections.

Rejection under 35 U.S.C. § 102(b) over Kuslich

As amended, independent claim 21 now requires the step of acutely securing the device to the spinal disc annulus. This limitation is neither taught nor suggested by Kuslich.

Nowhere does Kuslich teach any steps whatsoever for acutely securing the device **120** to the disc annulus, as is required of the claimed method. Accordingly, since Kuslich fails to disclose or suggest each and every limitation of the claimed invention, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 18, 19, and 21 over Kuslich in view of the amendment.

Rejection under 35 U.S.C. § 103(a) over Stubstad

As amended, independent claim 21 now requires the step of acutely securing the device to the spinal disc annulus. This limitation is neither taught nor suggested by Stubstad.

Nowhere does Stubstad teach any steps whatsoever for acutely securing his nuclear replacement device **120** to the disc annulus, as is required by the claimed method. The Examiner points to Stubstad's teaching of securing the nuclear replacement device to "other available tissues" as evidence that annular fixation would be obvious. Applicant disagrees.

Stubstad describes the negative effects of lateral stresses on the nuclear replacement disc after implantation. See col. 3, ll. 29-63. Stubstad also teaches providing a sidewall promoting the sealing of the rupture site in the posterior portion of the annulus fibrosus. Col. 13, ll. 19-23. Stubstad does not teach or suggest suturing the nuclear replacement to the annulus itself. Because the nuclear replacement requires attachment to at least one vertebra as discussed throughout Stubstad, and concomitant movement therewith, suturing the disc replacement to the annulus fibrosus would transfer large dynamic stresses on the annular wall, which would be concentrated at the point of suturing. The result of such suturing could be tearing of the annulus. In light of this observation, which would be obvious to one having ordinary skill in the art, it is respectfully submitted that one reading the Stubstad patent would not understand it to teach such a practice. The specification passage referenced by the Examiner, Col. 14, ll 48-50, recites:

The two segments [121, 122] may be further stabilized by tying them together by cords 129 or by suturing to one of the adjacent vertebrae or other available tissue.

It is respectfully submitted that Stubstad's reference to "tissue" does not explicitly include annular tissue, but rather refers to other tissue in the vicinity of the disc, as set forth at Col. 2, ll. 45-48:

This simple prosthetic disc is retained in place by reconstructed natural tissue surfaces, such as the cortical plate of the vertebral bodies, and the anterior and posterior longitudinal ligaments.

Accordingly, since Stubstad fails to teach or suggest the claimed invention, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 18-21 over Stubstad.

Double Patenting Rejection

Claim 21 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of commonly-assigned U.S. Patent 6,997,956. Without commenting on the propriety of the rejection as it applies to the claims as presently amended, and to advance prosecution, applicant encloses herewith a terminal disclaimer. It is respectfully requested that the rejection be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Date: May 31, 2006

By: 

Eric P. Raciti
Reg. No. 41,475